

TRANSMITTAL OF APPEAL BRIEF (Large Entity)

Docket No.
JEL 31040

In Re Application **Jose F. DDA**

Serial No.
09/526,547

Filing Date
March 16, 2000

Examiner
Vy Bui

Group Art Unit
3731

Invention: **STRUCTURE OF A PROSTHESIS INTENDED TO BE IMPLANTED IN A HUMAN OR ANIMAL PASSAGE AND PROSTHESIS WITH SUCH A STRUCTURE**

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on June 13, 2003

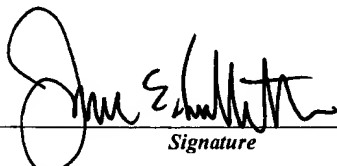
The fee for filing this Appeal Brief is: **\$320.00**

- ☒ A check in the amount of the fee is enclosed.
- ☒ The Commissioner has already been authorized to charge fees in this application to a Deposit Account. A duplicate copy of this sheet is enclosed.
- ☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 19-4375. A duplicate copy of this sheet is enclosed.

TECHNOLOGY CENTER R3700

JUL 28 2003

RECEIVED


Signature

Dated: July 22, 2003

James E. Ledbetter, Esq.
Registration No. 28,732
STEVENS, DAVIS, MILLER & MOSHER, LLP
1615 L. Street, NW, Suite 850
Washington, DC 20036
Tel.: 202.785.0100
Fax: 202.408.5200

I certify that this document and fee is being deposited on _____ with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Signature of Person Mailing Correspondence

Typed or Printed Name of Person Mailing Correspondence

CC:



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Appeals and Interferences

In re the Application of

Inventors: Jose FEDIDA

Appln No.: 09/526,547

Filed: March 16, 2000

For: STRUCTURE OF A PROSTHESIS INTENDED TO BE IMPLANTED
IN A HUMAN OR ANIMAL PASSAGE AND PROSTHESIS WITH
SUCH A STRUCTURE

RECEIVED

JUL 28 2003

TECHNOLOGY CENTER R3700

APPEAL BRIEF

On Appeal From Group Art Unit 3731

James E. Ledbetter

STEVENS DAVIS, MILLER & MOSHER, L.L.P.
1615 L Street, N.W., Suite 850
P.O. Box 34387
Washington, D.C. 20043-4387
Telephone: (202) 785-0100
Facsimile: (202) 408-5200

Attorney for Appellant

07/23/2003 KZEWIDIE 00000099 09526547

01 FC:1402

320.00 OP

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST	4
II. RELATED APPEALS AND INTERFERENCES	4
III. STATUS OF CLAIMS	4
IV. STATUS OF AMENDMENTS	4
V. SUMMARY OF THE INVENTION	4
VI. ISSUES	11
VII. GROUPING OF CLAIMS	12
VIII. ARGUMENT	12
IX. CONCLUSION	34
X. APPENDIX: THE CLAIMS ON APPEAL	36

TABLE OF AUTHORITIES

<i>Ex parte Levy</i> , 17 USPQ2d 1461 (Bd. Pat. App. & Inter. 1990)	17
<i>Ex parte Porter</i> , 25 USPQ2d 1144 (Bd. Pat. App. & Inter. 1992)	14
<i>Hodosh v. Block Drug Co., Inc.</i> , 786 F.2d 1136, 229 USPQ 182 (Fed. Cir. 1986)	25
<i>In re Mills</i> , 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) . .	24
<i>In re Rijckaert</i> , 9 F.3d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993)	18
<i>In re Robertson</i> , 169 F.3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999)	17

<i>In re Rouffet</i> , 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998)	25
<i>In re Royka</i> , 490 F.2d 981, 180 USPQ 580 (CCPA 1974)	24
<i>In re Vaeck</i> , 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)	25
Manual of Patent Examining Procedure, Eighth Edition, August 2001, §2131	16
Manual of Patent Examining Procedure, Eighth Edition, August 2001, §2141	25
Manual of Patent Examining Procedure, Eighth Edition, August 2001, §2173.05	14
Manual of Patent Examining Procedure, Eighth Edition, August 2001, §2112	17, 18
<i>Verdegaal Bros. v. Union Oil Co. of California</i> , 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987)	16

TABLE OF STATUTES

35 U.S.C. §112	13
37 C.F.R. §1.111	33
37 C.F.R. §1.116	13, 15

I. REAL PARTY IN INTEREST

The real party in interest is the assignee of the present application, Novatech SA, of Grasse Le Plan, France.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-40 have been presented for examination. Claims 1-17 have been cancelled and claims 18-40 remain pending. Of the pending claims, claims 20 and 31 are objected to and claims 18, 19, 21-30, and 32-40 stand finally rejected. Claims 18-40 form the subject matter of the present appeal.

IV. STATUS OF AMENDMENTS

The Amendment after Final Rejection of April 28, 2003 has not been entered.

V. SUMMARY OF THE INVENTION

The invention as defined by each of claims 18-40 is directed to a structure of a prosthesis intended for implantation in a human or animal vascular passage to preserve or reestablish a through passage along the vascular passage. This vascular prosthesis is

designed to be supple so that it may be folded for insertion and implantation into an artery and thereafter deployed reliably and safely within the artery.

More specifically, the invention of claim 18 defines a structure 2 of a prosthesis 1 intended to be implanted in a human or animal passage to provide a through-passage along the passage (specification page 7, lines 6-10). Structure 2 includes a mesh 4 that is at least partially of an approximately cylindrical shape and has at least one corrugated filament F forming approximately annular units UA linked together (page 8, lines 1-6, and Fig. 1). At least some corrugations ON, of corrugated filament F, from two respective adjacent units of annular units UA are linked together by a plurality of linking means 5 (page 8, lines 6-11, and Fig. 1). And at least some of linking means 5 may be rigid piece links 6A-6C (page 8, lines 29-33, and Figs. 2-4). Each of links 6A-6C is provided with a sole central portion 7 and two loops B1, B2, with one loop B1, B2 at each of the ends of central portion 7 (page 9, lines 18-22, and Figs. 2-4). Also, each of the two loops B1, B2 of a link 6A-6C allows (a) a first shape of an arc of a circle prior to linking and (b) a second shape of an entirely closed loop, in the linking position (page 9, line 26, through page 10, line 3, and Figs. 2-4). Moreover, each of the two closed loops B1, B2 of each link 6A-6C entraps in the linking position, with some clearance J,

a respective one of two corrugations ON, which are to be linked together (page 8, lines 29-37, and Figs. 2-4).

The invention of claim 19 defines the structure of claim 18, whereby each central portion 7 of a link 6A-6C is a straight central portion 7 (page 9, lines 18-20, and Figs. 2-3).

The invention of claim 20 defines the structure of claim 18 whereby each central portion 7 of a link 6A-6C comprises two straight partial portions 12, 13 which are not aligned and which are connected together to form an acute angle α (page 10, lines 13-17, and Fig. 4).

The invention of claim 21 defines the structure of claim 18 whereby for at least one of links 6A-6C, one of the two loops B1, B2 is defined in a first plane which differs from a second plane in which the other of the two loops B1, B2 is defined (page 10, lines 33-37).

The invention of claim 22 defines the structure of claim 18 whereby at least some of the corrugations ON are zigzags (page 11, lines 17-20, and Fig. 5).

The invention of claim 23 defines the structure of claim 18 whereby mesh 4 at least partially includes hexagonal mesh openings M2 (page 11, lines 21-26, and Fig. 6).

The invention of claim 24 defines the structure of claim 18 whereby at least one of links 6A-6C is radio-opaque (page 11, lines 2-5, and Fig. 1).

The invention of claim 25 defines the structure of claim 24 whereby links 6A-6C include a number of radio-opaque links 6C arranged longitudinally with respect to cylindrical mesh 4 (page 11, lines 9-13, and Fig. 1).

The invention of claim 26 defines the structure of claim 18 whereby prosthesis 1 is intended to be implanted in a human or animal passage to provide through-passage along the passage (page 7, lines 6-10, and Fig. 1).

The invention of claim 27 defines the structure of claim 26 whereby at least one impervious envelope 3 at least partially surrounds structure 2 (page 7, lines 22-25, and Fig. 1).

The invention of claim 28 defines the structure of claim 27 whereby impervious envelope 3 has a turned-back region for at least one of the ends of structure 2 (page 6, lines 24-29).

The invention of claim 29 also defines a structure 2 of a prosthesis 1 intended to be implanted in a human or animal passage to provide a through-passage along the passage (page 7, lines 6-10). Structure 2 includes a mesh 4 that is at least partially of an approximately cylindrical shape and has at least one corrugated filament F forming approximately annular units UA linked together

(page 8, lines 1-6, and Fig. 1). At least some corrugations ON, of corrugated filament F, from two respective adjacent units of annular units UA are linked together by a plurality of linking means 5 (page 8, lines 6-11, and Fig. 1). And at least some of linking means 5 may be rigid piece links 6A-6C (page 8, lines 29-33, and Figs. 2-4). Each of these links 6A-6C is provided with a single central portion 7 and two loops B1, B2, with one loop B1, B2 at each of the ends of central portion 7 (page 9, lines 18-22, and Figs. 2-4). Also, each of the two loops B1, B2 of a link 6A-6C allows (a) a first shape of an arc of a circle prior to linking and (b) a second shape of a partially closed loop that is just closed up enough to entrap the corrugation ON that is to be linked, in the linking position (page 9, line 26, through page 10, line 3, and Figs. 2-4). Moreover, each of the two closed loops B1, B2 of each link 6A-6C entraps in the linking position, with some clearance J, a respective one of two corrugations ON, which are to be linked together (page 8, lines 29-37, and Figs. 2-4).

The invention of claim 30 defines the structure of claim 29, whereby each central portion 7 of a link 6A-6C is a straight central portion 7 (page 9, lines 18-20, and Figs. 2-3).

The invention of claim 31 defines the structure of claim 29 whereby each central portion 7 of a link 6A-6C comprises two straight partial portions 12, 13 which are not aligned and which

are connected together to form an acute angle α (page 10, lines 13-17, and Fig. 4).

The invention of claim 32 defines the structure of claim 29 whereby for at least one of links 6A-6C, one of the two loops B1, B2 is defined in a first plane which differs from a second plane in which the other of the two loops B1, B2 is defined (page 10, lines 33-37).

The invention of claim 33 defines the structure of claim 29 whereby at least some of the corrugations ON are zigzags (page 11, lines 17-20, and Fig. 5).

The invention of claim 34 defines the structure of claim 29 whereby mesh 4 at least partially includes hexagonal mesh openings M2 (page 11, lines 21-26, and Fig. 6).

The invention of claim 35 defines the structure of claim 29 whereby at least one of links 6A-6C is radio-opaque (page 11, lines 2-5, and Fig. 1).

The invention of claim 36 defines the structure of claim 35 whereby links 6A-6C include a number of radio-opaque links 6C arranged longitudinally with respect to cylindrical mesh 4 (page 11, lines 9-13, and Fig. 1).

The invention of claim 37 defines the structure of claim 29 whereby prosthesis 1 is intended to be implanted in a human or

animal passage to provide through-passage along the passage (page 7, lines 6-10, and Fig. 1).

The invention of claim 38 defines the structure of claim 37 whereby at least one impervious envelope 3 at least partially surrounds structure 2 (page 7, lines 22-25, and Fig. 1).

The invention of claim 39 defines the structure of claim 38 whereby impervious envelope 3 has a turned-back region for at least one of the ends of structure 2 (page 6, lines 24-29).

The invention of claim 40 also defines a structure 2 of a prosthesis 1 intended to be implanted in a human or animal passage to provide a through-passage along the passage (page 7, lines 6-10). Structure 2 includes a mesh 4 that is at least partially of an approximately cylindrical shape and has at least one corrugated filament F forming approximately annular units UA linked together (page 8, lines 1-6, and Fig. 1). At least some corrugations ON, of corrugated filament F, from two respective adjacent units of annular units UA are linked together by a plurality of linking means 5 (page 8, lines 6-11, and Fig. 1). And at least some of linking means 5 may be rigid piece links 6A-6C (page 8, lines 29-33, and Figs. 2-4). Each of these links 6A-6C is provided with a single central portion 7 and more than two loops B1, B2 which are connected to central portion 7 (page 4, lines 24-28, page 9, lines 18-22, and Figs. 2-4). Also, each of the two loops B1, B2 of a

link 6A-6C allows (a) a first shape of an arc of a circle prior to linking and (b) a second shape of a closed loop, in the linking position (page 9, line 26, through page 10, line 3, and Figs. 2-4). Moreover, each of the two closed loops B1, B2 of each link 6A-6C entraps in the linking position, with some clearance J, a respective one of two corrugations ON, which are to be linked together (page 8, lines 29-37, and Figs. 2-4).

The above references to the specification and drawings are for illustration only and are not to be construed in any way as limiting the scope of the claims to the discussed embodiments.

VI. ISSUES

1. Whether claims 29 and 40 stand correctly rejected as being indefinite under 35 U.S.C. §112, second paragraph.

2. Whether claims 18, 19, 22, 26, 27, 29, 30, 33, 37, and 38 stand correctly rejected as being anticipated, under 35 USC §102(b), by Goicoechea et al. (US 5,609,627) (hereinafter referred to as Goicoechea).

3. Whether claims 18, 19, 22, 26, 27, 29, 30, 33, 37, and 38 stand correctly rejected as being unpatentable, under 35 USC §103(a), over Goicoechea.

4. Whether claims 23, 28, 34, and 39 stand correctly rejected as being unpatentable, under 35 USC §103(a), over Goicoechea.

5. Whether claims 21, 24, 25, 32, 35, and 36 stand correctly rejected as being unpatentable, under 35 USC §103(a), over Goicoechea in view of Lau et al. (US 5,873,906) (hereinafter referred to as Lau).

6. Whether the drawings stand correctly objected to for failing to show the features recited in lines 12-15 of claim 40.

7. Whether claims 20 and 31 stand correctly objected to for depending from a rejected base claim.

VII. GROUPING OF CLAIMS

Each of the claims stands or falls separately from the other claims.

VIII. ARGUMENT

A. Rejection of Claims 29 and 40 as Being Indefinite under 35 U.S.C. §112, Second Paragraph.

Claims 29 and 40 stand rejected for reciting the feature "said clearance" without the antecedent basis provided by first reciting this feature with an indefinite article, such as in the form of "a clearance." See Final Rejection, mailed February 13, 2003, page 2.

Appellant submitted an Amendment after Final Rejection on April 28, 2003, containing an amendment to claims 29 and 40. In

this amendment, Appellant changed the recitation of "said clearance" to "a clearance." However, this amendment was refused entry into the application, as indicated in the Advisory Action, mailed May 23, 2003.

Section 116(b) of the Patent Rules states that, after a final rejection, amendments may be made to comply with any requirement of form expressly set forth in a previous Office Action. 37 C.F.R. §116. The Final Rejection states on page 2:

Claims 29 (line 19) and 40 (line 17) recite the limitation "said clearance". There is insufficient antecedent basis for this limitation in the claim.

The above quoted passage makes clear that a requirement regarding the form of claims 29 and 40 was expressly set forth in the Final Rejection. Appellant submitted a timely amendment of claims 29 and 40 to comply with this requirement, in accordance with 37 C.F.R. §116(b).

Moreover, 37 C.F.R. §116(b) states that amendments presenting rejected claims in better form for consideration on appeal may be admitted. Appellant's amendment to replace the phrase "said clearance" with "a clearance," as required by the Final Rejection, presents the rejected claims in better form for consideration on appeal. Therefore, this amendment merits entry into the application.

Furthermore, 35 U.S.C. §112, second paragraph, states:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The Final Rejection does not identify any prospective indefiniteness created by Appellant's recitation of "said clearance." To the contrary, the Final Rejection expressly states that claims 29 and 40 are rejected because "said clearance" lacks sufficient antecedent basis.

As noted in the August 2001 publication of the Manual of Patent Examining Procedure (hereinafter referred to as MPEP), a claim is indefinite when it contains words or phrases whose meanings are unclear. MPEP §2173.05(e), first sentence. The failure to provide explicit antecedent basis for terms does not always render a claim indefinite. MPEP §2173.05(e), fifth sentence. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite. MPEP §2173.05(e), sixth sentence; and see *Ex parte Porter*, 25 USPQ2d 1144, 1146 (Bd. Pat. App. & Inter. 1992).

An examination of claims 29 and 40 reveals that the word "clearance" does not have an unclear meaning. Although the phrase "said clearance" lacks a proper antecedent basis under U.S. claim practice, the scope of each of claims 29 and 40 is reasonably ascertainable to those skilled in the art.

In accordance with the above discussion, Appellant submits that the amendments to claims 29 and 40, submitted in the Response dated April 28, 2003, comply with the requirements for entry of an amendment under 37 C.F.R. §116(b). Therefore, entry of the Appellant's amendments, submitted April 28, 2003, and reversal of the 35 U.S.C. §112, second paragraph, rejections of claims 29 and 40 are warranted.

B. Rejection of Claims 18, 19, 22, 26, 27, 29, 30, 33, 37, and 38 as Being Anticipated by Goicoechea.

Independent claim 18 recites:

A structure of a prosthesis intended to be implanted in a human or animal passage to provide through-passage along said passage, said structure comprising:

at least one mesh which, at least in part, is approximately cylindrical and comprises at least one corrugated filament forming approximately annular units linked together, at least some corrugations of said corrugated filament of two respective adjacent units of said annular units being linked together by a plurality of linking means, wherein at least some of said linking means comprise links which are made as a rigid piece,

wherein each of said links is provided with a sole central portion and two loops, one loop at each of the ends of said central portion,

wherein each of said two loops allows (a) a first shape of an arc of a circle prior to linking and (b) a second shape of an entirely closed loop, in the linking position,

wherein each of the two closed loops of each of said links entraps, in said linking position, with some clearance, a respective one of two of said corrugations, which are to be linked together.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131.

Goicoechea fails to disclose, *inter alia*, the claimed features whereby: (1) each of the links is provided with a sole central portion and two loops, one loop at each of the ends of the central portion, (2) each of the two loops allows (a) a first shape of an arc of a circle prior to linking and (b) a second shape of an entirely closed loop, in the linking position, and (3) each of the two closed loops of each of the links entraps, in the linking position, with some clearance, a respective one of two of the corrugations, which are to be linked together.

The Final Rejection states that Goicoechea discloses a stent formed by zigzag-shaped nitinol filaments that form approximately annular units linked together by links/loops 99c, rings 99d, or staples 99e (Final rejection, section 1, lines 4-9). Continuing, the Final Rejection states that "a staple connection is well known to include one single/sole straight central portion connecting two loops at both ends of the central portion" (Final Rejection, section 1, lines 9-10).

However, Goicoechea does not expressly disclose that the staple connection necessarily has one single/sole straight central portion connecting two loops at both ends of the central portion. The Final Rejection acknowledges the absence of such an express disclosure by stating the missing disclosure is "well known" to one of ordinary skill in the art.

If the 35 USC 102 rejection is based on an allegation that the claimed subject matter is inherently disclosed by Goicoechea, this rejection has not been supported by a *prima facie* case.

To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999); MPEP §2112, 3rd paragraph. Inherency, however, may not be established by probabilities or possibilities. *In re Robertson*, at 745, 1951; MPEP §2112, 3rd paragraph. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson*, at 745, 1951; MPEP §2112, 3rd paragraph. In relying upon a theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teaching of the applied

prior art. See *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990); MPEP §2112, 4th paragraph. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. See *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); MPEP §2112, 3rd paragraph.

In general, it may be possible for staples, such as those used in an office environment, to have a single straight central portion connecting two loops at both ends of the central portion. However, it is also possible for staples to have a central straight portion and two end portions that bend at about a 180-degree angle, so that the respective ends overlap the central portion and lie substantially flat against it. This is perhaps the most common way that photocopying machines and other automated stapling devices staple a group of pages. It is also possible for construction staples to have a central straight portion and two 90 degree bends near opposite ends of the straight portion. A construction staple of this type secures an object, such as a wire, to another object such as a wood stud. Additionally, it is possible for these staples to have ends that extend away from the central portion, after the stapling operation, as may be achieved by a common office-type stapler.

The Final Rejection does not provide a basis in fact or technical reasoning to reasonably support the determination that the inherent characteristic (i.e., staples having two loops at opposite ends) necessarily flows from the teaching of Goicoechea. As described above, a staple may secure two objects together by means other than enclosing a first object in a first loop, formed at one end of a central portion, and enclosing a second object in a second loop formed at an opposite end of the central portion. Because the extrinsic evidence does not make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art, the implied inherency theory fails to meet the evidentiary standard that is required to support a *prima facie* case of anticipation.

Moreover, Goicoechea's Fig. 4F and written description, when considered together, appear to disclose a means of securing apices 22 of two hoops 20 that is contrary to that proposed in the Final Rejection. As illustrated in Goicoechea's Fig. 4F, the staple appears to form a single loop in the form of a squashed oval circuit. And this interpretation of the illustration is supported by Goicoechea's express disclosure.

Goicoechea discloses that an apex 22 of each hoop 20 is secured to a juxtaposed apex 22 of a neighboring hoop 20 (col. 9,

lines 43-50). The securing means may be a staple 99e formed of wire, as shown in Fig 4F (col. 9, lines 58-61).

The American Heritage College Dictionary, fourth edition, 2002, defines the word "juxtapose" as "to place side by side." This same dictionary defines side by side to mean "next to each other" and defines "next" to mean "nearest in space or position." A first object that is located nearest in space or position to a second object is necessarily in contact with the second object. Based on these definitions, Goicoechea discloses that the two neighboring hoops 20 are in contact with one another when secured by staple 99e, and this is exactly how Goicoechea illustrates the structure.

Goicoechea's Fig. 4F shows the neighboring hoops 20 in contact with each other. Also shown by this figure, is a staple 99e encircling the two hoops 20. This staple forms a single closed loop circuit surrounding the two hoops 20.

Goicoechea's disclosed structure is not identical or even similar to Appellant's claimed structure. Claim 18 recites a linking means that has a sole central portion and two loops, with each loop formed at a separate end of the central portion. Additionally, claim 18 recites that each loop entraps a separate one of two corrugations that are to be linked together. The claimed structure makes it impossible for the two corrugations to

touch at the points where they are secured and substantially encircled by the linking means' loops. By contrast to the claimed structure, Goicoechea discloses that the apices of the two hoops 20 secured by staple 99e do touch when staple 99e secures them.

Furthermore, with regard to staple 99e, the Final Rejection states the following. Since the flexibility of a stent is required to facilitate the deployment of the device, Goicoechea's staples "should be partially or entirely closed loops to entrap the zigzag-shaped wire with some clearance" (Final Rejection, page 3, lines 10-15).

The Final Rejection does not assert that Goicoechea expressly discloses providing clearance between the entrapped wires and the staples. To the contrary, the Final Rejection states that some clearance should be provided to give the stent flexibility.

If the Final Rejection is positing that the knowledge attributed to one of ordinary skill in the art would lead such a person to modify Goicoechea's disclosed structure, Appellant submits that such an argument is inappropriate for an anticipation rejection. On the other hand, if the Final Rejection is positing that Goicoechea inherently discloses providing clearance between the staple loop and the entrapped

wire, Appellant submits that a statement as to what "should be" does not meet the requisite legal standard for substantiating a theory of inherency.

In accordance with the above discussion, Appellant submits that Goicoechea fails to disclose all of the claimed features either expressly or inherently. Therefore, allowance of claim 18 and all claims dependent therefrom is warranted.

Independent claim 29 recites features similar to those discussed above in connection with the rejection of claim 18. Claim 29 similarly stands rejected as being anticipated by Goicoechea. For similar reasons provided with respect to the rejection of claim 18, Appellant submits that Goicoechea does not disclose all of the features recited in claim 29. Furthermore, claim 29 recites a second shape of a partially closed loop that is just closed up to entrap the corrugation that is to be linked in the linking position. Therefore, allowance of claim 29 and all claims dependent therefrom is warranted.

Dependent claim 19 recites the structure of claim 18 whereby each central portion of a link is a straight central portion.

Dependent claim 22 recites the structure of claim 18 whereby at least some of the corrugations are zigzags.

Dependent claim 26 recites a prosthesis intended to be implanted in a human or animal passage to provide through-passage

along the passage. This prosthesis comprises at least one structure as specified in claim 18.

Dependent claim 27 recites the structure of claim 26 having additionally at least one impervious envelope at least partially surrounding the structure.

Dependent claim 30 recites the structure of claim 29 whereby each central portion of a link is a straight central portion.

Dependent claim 33 recites the structure of claim 29 whereby at least some of the corrugations are zigzags.

Dependent claim 37 recites a prosthesis intended to be implanted in a human or animal passage to provide through-passage along said passage. This prosthesis comprises at least one structure as specified in claim 29.

Dependent claim 38 recites the structure of claim 37 having additionally at least one impervious envelope at least partially surrounding the structure.

The additional respective features of claims 19, 22, 26, and 27 in combination with those of base claim 18 are also not disclosed by Goicoechea. Similarly, the additional respective features of claims 30, 33, 37, and 38 in combination with those of base claim 29 are not disclosed by Goicoechea. The features recited in the dependent claims depart further from the teachings of the reference and provide an independent basis for the

allowance of these dependent claims. Therefore, reversal of the rejections of claims 19, 22, 26, 27, 30, 33, 37, and 38 is warranted.

C. Rejection of Claims 18, 19, 22, 26, 27, 29, 30, 33, 37, and 38 as Being Unpatentable over Goicoechea.

To establish a *prima facie* case of obviousness, all claim features must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985, 180 USPQ 580, 583 (CCPA 1974). Additionally, the prior art must suggest the desirability of modifying or combining the references to achieve the claimed invention. *In re Mills*, 916 F.2d 680, 682, 16 USPQ2d 1430, 1432 (Fed. Cir. 1990).

With regard to the obviousness rejections of independent claims 18 and 29, the Final Rejection relies on the same reasoning for the rejections of these claims as provided for the anticipation rejections. However, the Final Rejection states, in essence, that if Goicoechea does not inherently disclose providing clearance between the staple 99e and the filament wire forming hoop 20, then it would have been obvious to one of ordinary skill in the art to modify Goicoechea's disclosed structure in this way (Final Rejection, page 3, line 10, through page 4, line 3). The basis for this conclusion is that such a

modified structure would provide a linking means allowing flexibility of Goicoechea's structure during its deployment in a tortuous passage (Final Rejection, page 4, lines 3-5).

When applying 35 U.S.C. §103, the references must be viewed without the benefit of impermissible hindsight vision afforded by the Applicant's disclosure. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986); MPEP §2141. To prevent such use of impermissible hindsight, the prior art must provide a motivation to combine or modify the references that create the case of obviousness. *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). Stated another way, the prior art must provide the motivation to make the claimed combination or modification. *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991) ("[A] proper analysis under §103 requires, *inter alia*, consideration of ... whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device...").

Goicoechea does not describe providing flexibility or suppleness for the purpose of deploying a stent in a tortuous passage. Moreover, Goicoechea does not recite any form of the root word "flex" in the disclosure.

However, Goicoechea does disclose making the stent resiliently compressible so that it can be implanted in an artery with the aid of a catheter. Specifically, Goicoechea discloses that the sinuous configuration of each turn 20 of the wire skeleton of stent 10 allows the prosthesis to be compressed resiliently radially inwards so that it can be received in a catheter for per cutaneous or cut down delivery to an intraluminal site in the infra renal section of the aortic artery (col. 10, lines 45-50). Goicoechea's structure does not rely on Appellant's claimed structure to provide its resilient compressibility and provides no suggestion to make the modification proposed in the Final Rejection.

Appellant respectfully submits that the teaching and motivation to make the claimed invention may be found only through the impermissible hindsight afforded by the present application. The Final Rejection provides no evidentiary support for the conclusion that the claimed invention is suggested or motivated by the prior art. Absent some actual suggestion or motivation provided by the prior art for making the proposed modification, Goicoechea's disclosure and the proposed modification are not properly combinable to render the claimed invention obvious. As a result, it is respectfully submitted that a *prima facie* case of obviousness has not been established.

Appellant further submits that the distinguishing features discussed above in connection with the anticipation rejections of claims 18 and 29 similarly patentably distinguish claims 18 and 29 from Goicoechea, with regard to the obviousness rejection. For brevity, that discussion is incorporated here by reference rather than by repetition.

In accordance with the above discussion, Appellant submits that Goicoechea fails to disclose or suggest all of the claimed features and the benefits accruing from them. Therefore, allowance of claims 18 and 29 and all claims dependent therefrom is warranted.

Furthermore, Appellant submits that Goicoechea's staples are very different from the claimed links for the following reasons:

- 1) Goicoechea's staple 99e has only one loop and does not have a central portion, whereas the claimed link has two loops and a central portion;

- 2) Goicoechea's staple entraps two corrugations, whereas the claimed link has two loops that each entrap a separate corrugation. Thus, the claimed link improves the suppleness of the structure by preventing the two corrugation filaments from rubbing together and by separating the two corrugations with some distance;

3) Goicoechea's staples 99e have limited suppleness since they firmly grip the filament, whereas the claimed links entrap the corrugations with a certain amount of clearance in the loops. Thus, the filaments can move around in the loops and thereby make the structure very supple. This makes it possible to avoid permanent creases which often exist in known connecting means, once the structure has been folded between its various possible positions. These permanent creases can reduce the cross-sectional area of the passageway that is to be created using the implanted prosthesis;

4) prior to linking, Goicoechea's staple 99e has the shape of a U, whereas the loop of the claimed link has the shape of an arc of a circle; and

5) the fitting of Goicoechea's staple 99e is liable to damage the filament. This is not the case with the claimed link because the fitting is different and the loops entrap the corrugations with clearance.

The features recited in dependent claims 19, 22, 26, 27, 30, 33, 37, and 38 are described above in connection with the anticipation rejections applied to these claims. For brevity, that description is incorporated here by reference.

The combination of features recited in the dependent claims with those recited in their respective base claims depart

further from the teachings of the applied art and provide an independent basis for the allowance of these dependent claims. Therefore, reversal of the rejections of claims 19, 22, 26, 27, 30, 33, 37, and 38 is warranted.

D. Rejection of Claims 23, 28, 34, and 39 as Being Unpatentable over Goicoechea.

Claim 23 recites the structure of independent claim 18 whereby the mesh at least partially comprises hexagonal mesh openings.

Claim 28 recites a prosthesis intended to be implanted in a human or animal passage to provide through-passage along the passage. This prosthesis comprises at least one structure as specified in claim 18 and at least one impervious envelope at least partially surrounding the structure. Additionally, the impervious envelope has a turned-back region at least at one of the ends of the structure.

Claim 34 recites the structure of claim 29, whereby the mesh at least partially comprises hexagonal mesh openings.

Claim 37 recites a prosthesis intended to be implanted in a human or animal passage to provide through-passage along the passage. This prosthesis comprises at least one structure as specified in claim 29 and at least one impervious envelope at

least partially surrounding the structure. Additionally, the impervious envelope has a turned-back region at least at one of the ends of the structure.

The features distinguishing independent claims 18 and 29 from Goicoechea are discussed above in sections VIII(B) and VIII(C). The combination of features recited in the dependent claims with those recited in their respective base claims depart even further from the teachings of the applied art and provide an independent basis for the allowance of these dependent claims. Therefore, reversal of the rejections of claims 23, 28, 34, and 39 is warranted.

E. Rejection of Claims 21, 24, 25, 32, 35, and 36 as Being Unpatentable over Goicoechea in View of Lau.

Claim 21 recites the structure of claim 18 whereby, in the case of at least one of the links, one of the two loops is defined in a first plane which differs from a second plane in which the other of the two loops is defined.

Claim 24 recites the structure of claim 18 whereby at least one of the links is radio-opaque.

Claim 25 recites the structure of claim 24 whereby the links comprise a number of radio-opaque links arranged longitudinally with respect to the cylindrical mesh.

Claim 32 recites the structure of claim 29 whereby, in the case of at least one of the links, one of the two loops is defined in a first plane which differs from a second plane in which the other of the two loops is defined.

Claim 35 recites the structure of claim 29 whereby at least one of the links is radio-opaque.

Claim 36 recites the structure of claim 35 whereby the links comprise a number of radio-opaque links arranged longitudinally with respect to the cylindrical mesh.

Claims 21, 24, and 25 depend from base claim 18 and claims 32, 35, and 36 depend from base claim 29. Features of independent claims 18 and 29 that distinguish them from Goicoechea are discussed above in sections VIII(B) and VIII(C). Lau has been applied in the rejection of these claims solely for teaching links made of a radio opaque material such as gold, platinum, or tantalum to connect two adjacent annular units of a zigzag-shaped wire (Final Rejection, page 5, last paragraph).

Since Goicoechea does not suggest all of the claimed features of independent claims 18 and 29 and since the dependent claims depart even farther from the teachings of the applied art, the combination of features recited in the dependent claims provide an independent basis for the allowance of these dependent

claims. Therefore, reversal of the rejections of claims 21, 24, 25, 32, 34, and 35 is warranted.

F. Objection to the Drawings for Failing to Show the Feature Recited in Lines 12-25 of Claim 40.

The Final Rejection states that the drawings must show the features recited in lines 12-15 of claim 40. An amendment to the drawings was submitted by Appellant on April 28, 2003. The Advisory Action, mailed May 23, 2003, states that this amendment would not be entered because: (1) it raises new issues that would require further consideration and search and (2) it would not place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

Claim 40 was added to the application by amendment in Appellant's Response, submitted on November 18, 2002. This Amendment fully complied with the requirements of 37 C.F.R. §1.111. As a result, all features recited in claim 40 were required to be examined prior to the issuance of the Final Rejection. As part of this examination, a search for the existence of these features in the prior art was required.

A new Fig. 7 was submitted in Appellant's amendment to the drawings illustrating the features identified in the Final Rejection as missing from the drawings. The Advisory Action does

not suggest that this amendment: (1) fails to illustrate the necessary features or (2) adds new matter to the specification.

Since the features of claim 40, illustrated in new Fig. 7, were required to be searched prior to the issuance of a Final Rejection, the statement that Fig. 7 would require further consideration and a new search is insupportable. Moreover, had the amendment to the drawings been entered, the objection to the drawings would have been overcome. Therefore, the proposed amendment necessarily would have placed the application in better form for appeal by materially reducing or simplifying the issues for appeal.

For these reasons, Appellant submits that entry of the drawing amendment and the amendment to the specification referencing proposed Fig. 7 is appropriate. Also, reversal of the objection to the drawings is warranted.

G. Objections to Claims 20 and 31 for Depending from a Rejected Base Claim.

For the reasons discussed in sections VIII(B) and VIII(C) above, base claims 18 and 29 are patentable over the disclosure and teachings of Goicoechea. Since a properly drafted claim depending from an allowable independent claim is also allowable,

allowance of claims 20 and 31 is appropriate. Therefore, reversal of the objections to claims 20 and 31 is warranted.

IX. CONCLUSION

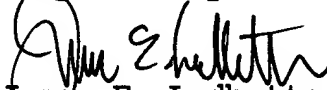
In accordance with the above discussion, entry of Appellant's proposed amendments to claims 29 and 40, the drawings, and the specification is appropriate. These amendments unquestionably place the application in better condition for issuance and are not alleged in the Final Rejection to introduce new matter. Since these amendments address the objection to the drawings, which arose from the features recited in claim 40, and the indefiniteness rejection of claim 40, allowance of claim 40 is warranted.

Also, as discussed above, the Final Rejection has failed to establish a *prima facie* case of Goicoechea's anticipation of claims 18, 19, 22, 26, 27, 29, 30, 33, 37, and 38. For similar reasons, the Final Rejection has failed to establish a *prima facie* case of the obviousness of claims 18, 19, and 21-39 based on Goicoechea alone or in view of Lau. The combined disclosures of Goicoechea and Lau fail to teach or suggest all claim features and fail to suggest the desirability of the claimed invention. Therefore, allowance of claims 18, 19, and 21-30, and 32-39 is warranted.

The allowance of base claims 18 and 29 would overcome the standing objections to dependent claims 20 and 31, respectively. Therefore, allowance of claims 20 and 31 is appropriate.

In view of the law and facts stated herein, it is respectfully submitted that all pending claims define patentable subject matter. Therefore, reversal of all outstanding grounds of the objections and rejections is respectfully solicited.

Respectfully submitted,



James E. Ledbetter

Registration No. 28,732

Date: July 22, 2003

JEL/DWW/att

ATTORNEY DOCKET NO. JEL 31040

STEVENS, DAVIS, MILLER & MOSHER, L.L.P.

1615 L Street, N.W., Suite 850

Washington, D.C. 20036

Telephone: (202) 785-0100

Facsimile: (202) 408-5200

X. APPENDIX: THE CLAIMS ON APPEAL

18. A structure of a prosthesis intended to be implanted in a human or animal passage to provide through-passage along said passage, said structure comprising:

at least one mesh which, at least in part, is approximately cylindrical and comprises at least one corrugated filament forming approximately annular units linked together, at least some corrugations of said corrugated filament of two respective adjacent units of said annular units being linked together by a plurality of linking means, wherein at least some of said linking means comprise links which are made as a rigid piece,

wherein each of said links is provided with a sole central portion and two loops, one loop at each of the ends of said central portion,

wherein each of said two loops allows (a) a first shape of an arc of a circle prior to linking and (b) a second shape of an entirely closed loop, in the linking position,

wherein each of the two closed loops of each of said links entraps, in said linking position, with some clearance, a respective one of two of said corrugations, which are to be linked together.

19. The structure as claimed in claim 18, wherein each central portion of a link is a straight central portion.

20. The structure as claimed in claim 18, wherein each central portion of a link comprises two straight partial portions which are not aligned and which are connected together to form an acute angle.

21. The structure as claimed in claim 18, wherein, in the case of at least one of said links, one of the two loops is defined in a first plane which differs from a second plane in which the other of the two loops is defined.

22. The structure as claimed in claim 18, wherein at least some of said corrugations are zigzags.

23. The structure as claimed in claim 18, wherein said mesh at least partially comprises hexagonal mesh openings.

24. The structure as claimed in claim 18, wherein at least one of said links is radio-opaque.

25. The structure as claimed in claim 24 wherein said links comprise a number of radio-opaque links arranged longitudinally with respect to said cylindrical mesh.

26. A prosthesis intended to be implanted in a human or animal passage to provide through-passage along said passage, and which comprises at least one structure as specified in claim 18.

27. The prosthesis as claimed in claim 26, and additionally comprising at least one impervious envelope at least partially surrounding said structure.

28. The prosthesis as claimed in claim 27, wherein said impervious envelope has a turned-back region at least at one of the ends of said structure.

29. A structure of a prosthesis intended to be implanted in a human or animal passage to provide through-passage along said passage, said structure comprising:

at least one mesh which, at least in part, is approximately cylindrical and comprises at least one corrugated filament forming approximately annular units linked together, at least some of the corrugations of said corrugated filament of two respective adjacent units of said annular units being linked

together by a plurality of linking means, wherein at least some of said linking means comprise links which are made as a rigid piece,

wherein each of said links is provided with (a) a single central portion, and (b) two loops comprising one loop at each of the ends of said central portion, wherein each of said two loops allows a first shape of an arc of a circle prior to linking and a second shape of a partially closed loop that is just closed up to entrap the corrugation that is to be linked, in the linking position, and

wherein each of the two loops of each of said links entraps, in said linking position, with said clearance, a respective one of two of said corrugations, which are to be linked together.

30. The structure as claimed in claim 29, wherein each central portion of a link is a straight central portion.

31. The structure as claimed in claim 29, wherein each central portion of a link comprises two straight partial portions which are not aligned and which are connected together to form an acute angle.

32. The structure as claimed in claim 29, wherein, in the case of at least one of said links, one of the two loops is

defined in a first plane which differs from a second plane in which the other of the two loops is defined.

33. The structure as claimed in claim 29, wherein at least some of said corrugations are zigzags.

34. The structure as claimed in claim 29, wherein said mesh at least partially comprises hexagonal mesh openings.

35. The structure as claimed in claim 29, wherein at least one of said links is radio-opaque.

36. The structure as claimed in claim 35 wherein said links comprise a number of radio-opaque links arranged longitudinally with respect to said cylindrical mesh.

37. A prosthesis intended to be implanted in a human or animal passage to provide through-passage along said passage, and which comprises at least one structure as specified in claim 29.

38. The prosthesis as claimed in claim 37, and additionally comprising at least one impervious envelope at least partially surrounding said structure.

39. The prosthesis as claimed in claim 38, wherein said impervious envelope has a turned-back region at least at one of the ends of said structure.

40. A structure of a prosthesis intended to be implanted in a human or animal passage to provide through-passage along said passage, said structure comprising:

at least one mesh which, at least in part, is approximately cylindrical and comprises at least one corrugated filament forming approximately annular units linked together, at least some corrugations of said corrugated filament of two respective adjacent units of said annular units being linked together by a plurality of linking means, wherein at least some of said linking means comprise links which are made as a rigid piece,

wherein each of said links is provided with (a) a single central portion, and (b) more than two loops which are connected to said central portion, wherein each of said loops allows a first shape of an arc of a circle prior to linking and a second shape of a closed loop in the linking position, and

wherein each of the two loops of each of said links entraps, in said linking position, with said clearance, a respective one of two of said corrugations, which are to be linked together.